BRONKAID MAX- ephedrine sulfate tablet, coated Foundation Consumer Healthcare LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Bronkaid® Max

. .

Drug Facts

Active ingredient (in each caplet)

Ephedrine sulfate 25 mg

Purpose

Bronchodilator

Uses

- for temporary relief of mild symptoms of intermittent asthma:
- wheezing
- tightness of chest
- shortness of breath

Warnings

Asthma alert

Because asthma may be life threatening, see a doctor if you

- are not better in 60 minutes
- get worse
- need more than 6 caplets in 24 hours
- use more than 4 caplets in 24 hours for 3 or more days a week
- have more than 2 asthma attacks in a week

These may be signs that your asthma is getting worse.

• This product will not give you asthma relief as quickly as an inhaled bronchodilator.

Do not use

- unless a doctor said you have asthma
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- ever been hospitalized for asthma
- heart disease
- high blood pressure

- diabetes
- thyroid disease
- seizures
- narrow angle glaucoma
- a psychiatric or emotional condition
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking prescription drugs for asthma, obesity, weight control, depression, or psychiatric or emotional conditions
- taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as for allergy, cough-cold, or pain)

When using this product

- your blood pressure or heart rate may go up. This could increase your risk of heart attack or stroke, which may cause death.
- your risk of heart attack or stroke increases if you:
 - have a history of high blood pressure or heart disease
 - take this product more frequently or take more than the recommended dose
- avoid foods or beverages that contain caffeine
- avoid dietary supplements containing ingredients reported or claimed to have a stimulant effect

Stop use and ask a doctor if

- your asthma is getting worse (see Asthma Alert)
- you have difficulty sleeping
- you have a rapid heart beat
- you have tremors, nervousness, or seizure

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- adults and children 12 years and over: take 1 caplet every 4 hours as needed. Do not take more than 6 caplets in 24 hours or as directed by a doctor.
- children under 12 years of age: do not use

Other information

store at 20-25°C (68-77°F)

Inactive ingredients

dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, sodium starch glycolate, stearic acid, talc

Questions or comments?

call **1-855-565-9800** weekdays 9 AM to 5 PM EST

Dist. by: Foundation Consumer Healthcare, LLC.

PRINCIPAL DISPLAY PANEL - 24 Caplet Blister Pack Carton

NDC 69536-250-24

BRONKAID® MAX

NEW FORMULA

Ephedrine Sulfate 25 mg/ Bronchodilator

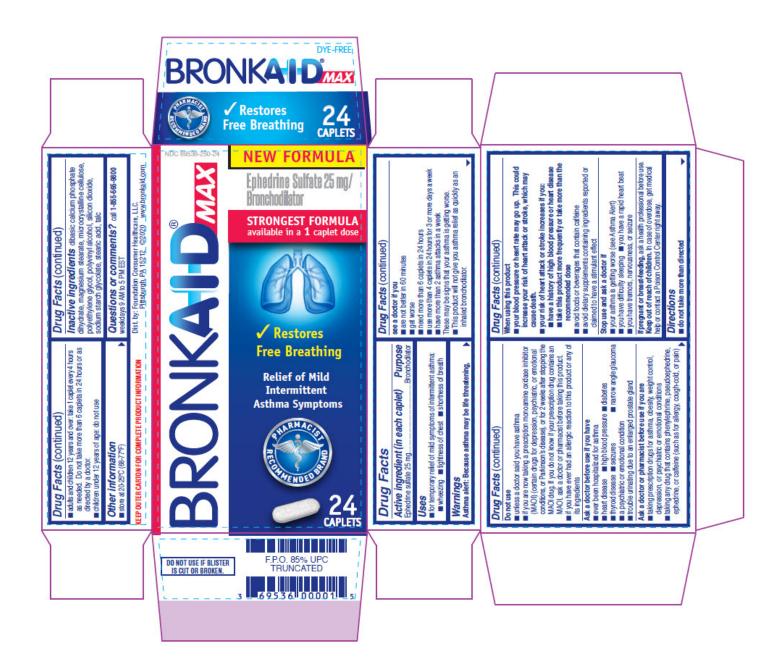
STRONGEST FORMULA available in a 1 caplet dose

RestoresFree Breathing

Relief of Mild Intermittent Asthma Symptoms

PHARMACIST RECOMMENDED BRAND

24 CAPLETS



BRONKAID MAX

ephedrine sulfate tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69536-250
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EPHEDRINE SULFATE (UNII: U6 X6 1U5ZEG) (EPHEDRINE - UNII:GN8 3C131XS)	EPHEDRINE SULFATE	25 mg	

Inactive Ingredients		
	Ingredient Name	Strength

DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	16 mm	
Flavor		Imprint Code	BRONK25	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69536-250-24	4 in 1 CARTON	09/01/2020		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:69536-250- 60	5 in 1 CARTON	09/01/2020		
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/01/2020	

Labeler - Foundation Consumer Healthcare LLC (079675882)

Revised: 6/2020 Foundation Consumer Healthcare LLC